REMARKS

Reconsideration of this application is requested. Claims 47-54 are in the case.

I. CLAIM OBJECTIONS

Claim 49 has been objected to on the ground that the drawing of the compound is unclear. In response, all of the claims in this application have been re-presented with clarified drawings. Withdrawal of this objection is now respectfully requested.

II. DOUBLE PATENTING

Claims 47-54 stand rejected on obviousness-type double patenting grounds as allegedly unpatentable over claim 3 of U.S. Patent 6,020,322. In response, it is respectfully requested that this rejection be placed in abeyance until the present application is otherwise in condition for allowance. At that time, consideration will be given as to whether or not to submit a Terminal Disclaimer.

III. THE 35 U.S.C. § 112, FIRST PARAGRAPH, REJECTION

Claims 47-54 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was allegedly not described in the specification in such a way as to reasonably to convey to one skilled in the relevant art that the inventors at the time the application was filed had possession of the claimed invention. This rejection is respectfully traversed.

The rejection asserts that the pending claims contain subject matter which was not "described" in the specification in such a way as to convey to one skilled in the art

that the inventors at the time the application was filed had possession of the claimed invention. Review of the written description, beginning at page 7 of the application reveals that the subject matter of claims 47-54 is described in a way which conveys to the reader that the inventors had possession of the invention at the time the application was filed. For example, at page 30, beginning at line 3, the specification states:

> "The compositions of the present invention may be administered to an animal either before or after exposure to radiation, sunlight or mutagens. The acyl derivative form of the deoxyribonucleosides provides an orally effective means for delivery of deoxyribonucleosides to tissues. These derivatives may also be given parenterally or topically. Administration of the derivatives avoids the problem of rapid catabolism by gastrointestinal, liver and plasma enzymes."

At page 32 in the second complete paragraph, the specification states:

> "There are conditions other than radiation damage in which exogenous deoxyribonucleosides or derivatives thereof have useful therapeutic applications.
>
> Deoxyribonucleic acid has been used to accelerate wound cicatrization or healing, and also to accelerate liver regeneration in experimental animals. It is likely that in these situations, as well as in the situation where DNA is used to promote survival after irradiation of animals, the DNA is serving as a storage depot for deoxyribonucleosides, which gradually releases the deoxyribonucleotides, and deoxyribonucleosides during enzymatic degradation."

At page 34, beginning in the third complete paragraph, the specification states:

> "For treatment of radiation-induced cellular damage or sunburn, or to enhance wound healing, preferred dosages include amounts of the acyl derivatives equivalent to 10 to 1000 mg of 2'-deoxyadenosine, 10 to 1000 mg of 2'-deoxyguanosine, 10 to 1000 mg of 2'-deoxycytidine and 10 to 1000 mg of 2'-deoxythymidine. For example, the composition may comprise 13-1330 mg of 3',5'-diacetyl-2'-deoxyadenosine, 13-1310 mg of 3',3'-diacetyl-2'-deoxyguanosine, 14-1370 mg of 3',5'-diacetyl-2'-deoxycytidine and 14-1350 mg of 3',5'-diacetyl-2'-deoxythymidine. As is understood in the art, in calculating such dosages, the equivalent amount of the 2'-deoxyribnucleoside alone is considered, i.e., the acyl substituent and acid addition portion of any pharmaceutically acceptable salt are not included in the calculation."

Of particular relevance to claim 54 is the description at page 34 in the first complete paragraph, which states:

> "Compositions within the scope of the invention include those which contain mixtures of the acyl derivatives of the deoxyribonucleosides in amounts effective to achieve its intended purpose. Such compositions may contain 0 to 50 mole percent of the acyl derivative of deoxycytidine, 0 to 50 mole percent of the acyl derivative of deoxyguanosine, 0 to 50 mole percent of the acyl derivative of deoxythymidine and 0 to 50 mole percent of the acyl derivative of deoxyadenosine, with the proviso that the total content of the acyl deoxyribonucleosides adds up to 100 mole percent."

The first paragraph of 35 USC 112 requires that the "specification shall contain a written description of the invention". Decided U.S. case law has established that the written description requirement is separate and distinct from the enablement requirement. *Vas-Cath Inc. v. Mahurkar*, 93 F.2d 1555, 1560, 19 USPQ 2d 1111, 1115 (CAFC 1991). As stated in Paragraph I of The Interim Guidelines for Examination of Patent Applications under The 35 USC 112 First Paragraph Written Description Requirement (June, 1998), the written description requirement has several policy objectives. The Guidelines state, in part:

> "[T]he 'essential goal' of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed. Another objective is to put the public in possession of what the applicant claims as the invention....
> To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. This requirement of the Patent Act promotes the progress of the useful arts by ensuring that patentees adequately describe their inventions in their patent specifications for the benefit of the public in exchange for the right to exclude others from practicing the invention for the duration of the patent term."

As evidenced by the quotes from the specification presented above, the specification clearly places the reader in possession of the invention. Under the

Guidelines, all that is required to satisfy the written description requirement is that the patent specification "describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention." One of ordinary skill, upon reading the specification of the present application, would reasonably conclude that the present inventors had possession of the claimed invention.

On page 4 of the Action, the Examiner has stated:

> "Moreover, the support in the specification is not adequate for the claim to the treatment or prevention of cellular damage caused by any mutagen".

Whether or not the written description aspect of the statute is complied with in a patent specification is not determined by the "support" in the specification for the claimed invention. Data or other "support" is not required to satisfy the written description requirement. All that is required to satisfy the written description requirement, as noted earlier, is that the patent specification "describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. It is believed that the reader would not reasonably conclude from the present written description that the description is limited only to treatment of radiation induced cellular damage or sunburn with the compounds of the invention.

The Examiner alludes to support for the breadth of claims later on page 4 of the Action, where it is stated:

> "To provide adequate support to the breadth of the claims, Applicant would have to establish that over a period of time, a population of individuals subjected to a variety of the types of mutagenic substances cited above, were treated for or did not incur any cellular damage. The data presented shows mortality rates after

exposure to gamma radiation which may be adequately correlative for the species of treating radiation induced cellular damage; however, this does not correlate to a prevention or treatment of cellular damage caused by any mutagen as broadly claimed."

Again, data presented in the specification is not determinative as to whether the specification provides a written description of the claimed invention. For the reasons discussed above, it is believed that the specification does provide a written description of the claimed invention, and withdrawal of the rejection for the above-discussed reasons is believed to be in order. Such action is respectfully requested.

Allowance of the application is awaited.

Respectfully submitted,

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